

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

2:16 MD 1203

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In September, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Jeffrey T. Kuvin, M.D., F.A.C.C., F.A.H.A., F.A.C.P. Based on an echocardiogram dated February 13, 1998, Dr. Kuvin attested in Part II of Ms. Molden's Green Form that she suffered from severe mitral regurgitation, surgery to repair or replace the aortic and/or mitral valve(s) following the use Pondimin® and/or Redux™, New York Heart Association Functional Class III symptoms, and an ejection fraction of less than 40% at any time six months or

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Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

later after valvular repair or replacement surgery.³ Based on such findings, claimant would be entitled to Matrix A-1, Level V benefits in the amount of \$1,158,427.⁴

Dr. Kuvin also attested in claimant's Green Form that Ms. Molden did not suffer from mitral annular calcification. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). As the Trust does not contest Ms. Molden's entitlement to Level V benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In July, 2004, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala concluded that there was no reasonable medical basis for Dr. Kuvin's finding that claimant did not have mitral annular calcification. In support of this conclusion, Dr. Penkala explained: "I thought that there was evidence of

3. Dr. Kuvin also attested that claimant suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left ventricular dimension, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 40% to 49%. These conditions, however, are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for payment at Matrix Levels III or IV, had New York Heart Association Functional Class III or Class IV symptoms, underwent surgery to repair or replace the aortic and/or mitral valve(s), and had a left ventricular ejection fraction of less than 40% six months or more after valvular repair or replacement surgery. See Settlement Agreement § IV.B.2.c.(5)(b).

mild [mitral annular calcification] on the apical [four chamber] view on the study dated 2/13/98."

Based on Dr. Penkala's finding that claimant had mitral annular calcification, the Trust issued a post-audit determination that Ms. Molden was entitled only to Matrix B-1, Level V benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In contest, claimant argued that her echocardiogram report of February 13, 1998 did not indicate any finding of mitral annular calcification and noted that Dr. Kuvin attested in her Green Form that no mitral annular calcification was present. Claimant also included a letter from Dr. Kuvin in which he stated, after reviewing the echocardiogram, that:

I do not see evidence of mitral annular calcification in [the] study. Specifically, I believe there is no mitral annular calcification in the apical 4-chamber view. In addition, I have reviewed the echocardiogram with my colleague, Dr. Natesa Pandian (Director, Cardiovascular Imaging and Hemodynamics Laboratory at Tufts-New England Medical Center, Level III trained in echocardiography in accordance with the American Society of Echocardiography), and he concurs with my impression of the study.⁶

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Molden's claim.

6. Claimant did not include any documentation from Dr. Pandian
(continued...)

Claimant also asserted that the auditing cardiologist's finding of mitral annular calcification was "highly questionable and clearly inconclusive."

The Trust then issued a final post-audit determination, again determining that Ms. Molden was entitled only to Matrix B-1, Level V benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Molden's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5246 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 15, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after

6. (...continued)
in her contest materials.

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are
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the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Molden reasserts the arguments she made in contest. Claimant also contends that there is a reasonable medical basis for Dr. Kuvin's finding that she

7. (...continued)
conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

did not have mitral annular calcification because the determination is "subjective" and she has submitted "the opinion of more than one qualified cardiologist that there is no evidence of [mitral annular calcification] on the 2/13/98 study" In addition, claimant includes a supplemental verified statement from Dr. Kuvin, wherein he confirmed his earlier findings and opined that "the presence of sub-mitral calcification (as noted on original echocardiogram report) does not support the claim [of] mitral annular calcification."

In response, the Trust argues that the findings on the echocardiogram report of "mild calcification/fibrosis of mitral chordae" and that "[t]he mitral leaflets are mildly thickened with restricted motion (posterior leaflet is fixed)" support a finding of mitral annular calcification. The Trust also contends that Dr. Kuvin's statement regarding Dr. Pandian's observations is hearsay and should not be permitted.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have mitral annular calcification. Specifically, Dr. Vigilante determined that:

There was obvious evidence of mitral annular calcification. This was manifested by increased echoes and increased reflectance of the echoes noted in several areas along the annulus. In the parasternal long axis view, it was obvious that the posterior portion of the mitral annulus was calcified. For example, this was easily seen at time 16:36:55 on the tape. Mitral annular

calcification was easily seen on the apical 4-chamber view. The posterior as well as medial areas of the mitral annulus could be seen as calcified. For example, this was noted at time 16:41:27 on the tape. In addition, the posterior portion of the mitral annulus could be seen on an off axis apical 4-chamber view. This was noted at time 15:43:36 on the tape. Calcification of the posterior annulus was noted in the apical 2-chamber view. This was seen at time 16:45:27 on the tape. In all of these views, classic mitral annular calcification was noted. The increased reflectance of echoes was separate from the posterior pericardium. The increased reflectance of echoes was also separate from the aortic annulus.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest the analysis provided by the auditing cardiologist. Specifically, Dr. Penkala determined that there was evidence of mitral annular calcification on claimant's echocardiogram. Although claimant characterized Dr. Penkala's findings as questionable and inconclusive, she did not identify any particular error in Dr. Penkala's conclusions. Instead, she relies on the verified statements of Dr. Kuvin, who simply reaffirmed his earlier findings, and the report of her echocardiogram, which does not state specifically that claimant did not have mitral annular calcification.⁸ Mere disagreement with the auditing cardiologist without identifying any specific

8. In addition, in responding to the Trust's argument that the echocardiogram report identified mitral annular calcification, Dr. Kuvin stated "in my opinion, the presence of sub-mitral calcification (as noted on original echocardiogram report) does not support the claim [of] mitral annular calcification." Dr. Kuvin, however, does not provide a basis for this opinion.

errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her Matrix A-1 claim.

Moreover, Dr. Vigilante reviewed claimant's echocardiogram and determined that "the echocardiogram of February 13, 1998 shows definite mitral annular calcification noted on multiple echocardiographic views." According to Dr. Vigilante, "[a]n echocardiographer could not reasonably conclude that mitral annular calcification was not present on this study even taking into account inter-reader variability." Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. On this basis as well, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have mitral annular calcification. Therefore, we will affirm the Trust's denial of Ms. Molden's claim for Matrix A-1 Benefits.